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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,964	12/15/2005	Jurgen Dorn	1016710009P	1085

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EXAMINER	
YABUT, DIANE D	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
03/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,964	DORN, JURGEN	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8 and 10-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8 and 10-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/15/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 07/16/2008.

The examiner acknowledges the amendments made to the claims.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 01/15/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5, 7-8, and 10-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Helgerson** (U.S. Patent No. **5,695,499**) in view of **Hancock** (U.S. Patent No. **6,702,802**) and **Wijay** (U.S. Patent No. **5,690,643**).

Claims 1-5, 7-8, 10-18, 20-28: Helgerson discloses an inner catheter including a wire coil **32**, the wire coil having an outer tube or lubricious coating or fluid disposed around at least the intermediate region ("covering," see col. 4, lines 61-67), a thermoplastic elastomeric sheath **50** disposed around at least a portion of the inner catheter and having a silicone material disposed between the outer tube and sheath (col. 5, line 66 to

col. 6, line 5), the sheath being retractable in a proximal direction relative to the inner catheter (col. 7, lines 1-3, Figures 4-8). An atraumatic tapered tip **31** is positioned at the distal end of the catheter, the tip being formed as part of the sheath and the sheath being connected to the inner catheter (Figure 2). Helgerson also discloses a medical device or self-expanding stent **10** (col. 3, line 67) being maintained in position between the sheath and the inner catheter, the medical device being radially compressed and subsequently releasable by retraction of the sheath in a proximal direction relative to the inner catheter, and an actuation device **60** connected to a proximal end of the inner catheter and the sheath, configured to retract the sheath in a proximal direction relative to the inner catheter (Figures 2 and 6-8, col. 6, line 62 to col. 7, line 16).

Although Helgerson acknowledges that the wire coil **32** has closely spaced coils (col. 4, lines 14-17) or may have spaces that exist between some of the coils (col. 4, lines 35-38), it is not expressly disclosed to have a closed-coil structure at an intermediate region of the wire coil and an open-coil structure at proximal and distal regions of the wire coil.

Hancock teaches a catheter with a wire coil having a closed-coil structure at an intermediate region **279** and an open-coil structure at proximal and distal **277** regions (see Figure 16). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a closed-coil structure at an intermediate region and an open-coil structure at proximal and distal regions of the inner catheter, as taught by Hancock, to Helgerson in order to facilitate delivery of the device through the body and to provide a gradual change in stiffness when moving from region to the other (col. 14, lines 53-67).

Helgerson also does not disclose the wire coil being disposed around an inner tube.

Wijay teaches a stent delivery system comprising an open coil **36** surrounding an inner tube **19** defining a guide wire lumen and a medical-device-receiving annulus around a distal portion, the coil defining a liquid flow path from the proximal end to the distal end of a catheter including a radially-extending portion through the open-coil structure and an annular flow path bounded by the inner tube and the wire coil, in order to permit perfusion to the device so that drugs or blood or other fluid can be carried through the device which may reduce patient discomfort (Figure 5, col. 2, lines 15-36, col. 4, lines 1-11 and 37-42). The distal end of the inner tube **19** also extends to a point distal of the distal end of the wire coil, and defines an inner guidewire lumen, and a medical-device-receiving annulus at the distal portion of the inner tube which is distal of the distal end of the wire coil and proximal of the distal end of the inner tube. It would have been obvious to one of ordinary skill in the art at the time of invention to provide an open-coil structure, as taught by Wijay, to Helgerson in order to permit perfusion and reduce patient discomfort, as well as to maintain a guidewire within the device when passing it through.

Claim 19: Helgerson discloses a flexible tip **31** (col. 5, lines 20-29), although does not expressly disclose that it be formed of polyurethane. It would have been obvious to one of ordinary skill in the art at the time of invention to have the tip be made of polyurethane material, since it was well known in the art as a suitable biocompatible polymer.

3. Claims 29-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Helgerson** (U.S. Patent No. **5,695,499**) in view of **Hancock** (U.S. Patent No. **6,702,802**) and **Wijay** (U.S. Patent No. **5,690,643**), as applied to claim 24 above, and further in view of **Dwyer** (U.S. Pub. No. **20020016597**).

Claims 29-32: Helgerson, Hancock, and Wijay disclose the claimed device, except for a pusher element and a push rod disposed about the inner tube at a proximal region thereof, a distal end of the push rod joined to a proximal end of the wire coil.

Dwyer teaches a distal end of the wire coil being joined to a pusher element **40** disposed about a distal region of the inner tube that includes a shoulder, and a stent bed **42** being defined along a distal region of the inner tube between the shoulder and a distal end of the inner tube (Figure 2, page 6, paragraph 50) and a push rod disposed about the inner tube at a proximal region thereof, a distal end of the push rod joined to a proximal end of the wire coil (page 1, paragraph 8; page 2, paragraph 13). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a pusher element or push rod, as taught by Dwyer, to Helgerson, Hancock, and Wijay since it was well known in the art to efficiently advance a stent with a pusher in cooperation with a retraction sheath.

Claims 34-36: Helgerson, Hancock, and Wijay disclose the claimed device, except for the actuating device including a first member connected to the inner catheter and a second member connected to the sheath, the second member including a locking member configured to prevent relative movement between the inner catheter and the sheath.

Dwyer teaches an actuating device **58** including a first member connected to the inner catheter and a second member connected to the sheath, the second member including a locking member configured to prevent relative movement between the inner catheter and the sheath (page 6, paragraphs 49-50). An open position of the actuating device includes the first member spaced apart from the second member and wherein a closed position of the actuation device includes the first member adjacent to the second member (page 6, paragraphs 49-50). The second member includes a luer member in fluid communication with the inner catheter (page 6, paragraphs 49-50). It would have been obvious to one of ordinary skill in the art at the time of invention to provide first and second members in the actuating device, as taught by Dwyer, to Helgerson, Hancock, and Wijay in order to prevent inadvertent deployment of the stent.

4. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Helgerson** (U.S. Patent No. **5,695,499**) in view of **Hancock** (U.S. Patent No. **6,702,802**) and **Wijay** (U.S. Patent No. **5,690,643**), as applied to Claim 24 above, and further in view of **Klemm** (U.S. Patent No. **5,458,615**).

Claim 33: Helgerson, Hancock, and Wijay disclose the claimed device, except for a radiopaque marker band being attached to an inner surface of a distal end of the sheath, although Helgerson does disclose radiopaque markers **36** and **37** disposed on the coil (Figure 4).

Klemm teaches a radiopaque marker band being attached to an inner surface of a distal end of a sheath so that the physician can determine when the sheath has been

withdrawn a sufficient distance so as not to interfere with the deployment of the stent (col. 9, lines 25-35). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a radiopaque marker on the sheath, as taught by Klemm, to Helgerson, Hancock, and Wijay in order to avoid interference with the deployment of the stent.

Response to Arguments

5. Applicant's arguments filed 07/16/2008 have been fully considered but they are not persuasive.

6. Applicant argues that the coil taught by Hancock only refers to a distal region having an open and closed structures, and therefore does not teach an intermediate region having a closed-coil structure. However, as seen in Figure 16 of Hancock, at the distal end (near **277**) there is an open coil, and the section proximal to this (at **279**) may be reasonably considered as an "intermediate region" that has a closed coil structure.

7. Applicant also argues that one skilled in the art would not modify Helgerson with Hancock since a guidewire moving through the coil would be pushed through the open regions and therefore render the device inoperable. However, as maintained above, Hancock does teach spaces between the coils, and therefore having both the open and closed coil configurations of Hancock with the device of Helgerson would advantageously provide a gradual change in stiffness when moving from region to the other (col. 14, lines 53-67).

8. Lastly, applicant argues that there is no motivation for modifying Helgerson with Wijay to add an additional inner tube. However, as maintained above, it would have been obvious to one of ordinary skill in the art at the time of invention to provide an open-coil structure, as taught by Wijay, to Helgerson in order to permit perfusion and reduce patient discomfort, as well as to maintain a guidewire within the coil when passing it through the coil.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734